

## Do I have to submit my project to the IRB?

Use this form to determine whether your project is considered "human subjects' research".

If you still aren't sure, please reach out to the IRB ([irb@roanoke.edu](mailto:irb@roanoke.edu)).



\* Required

\* This form will record your name, please fill your name.

### What to expect

This form will walk you through various federal definitions to help you determine whether your project is technically classified as "research", and if so, if it constitutes "human subjects' research".

As such, the first section will ask you questions about your project to determine if it qualifies as "research".

From there, you may or may not be redirected towards the second section (depending on your answers to the first few questions). The second section will ask you questions about your project to determine if it qualifies as "human subjects research".

### **Does your project involve "research"?**

Respond to the following questions to determine whether your project involves "research", according to the Common Rule and the Belmont Report.

**Research** refers to "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (The Common Rule) and/or "an activity designed to test a hypothesis [and] permit conclusions to be drawn" through a formal study plan with a set of procedures to reach an objective (the Belmont Report).

## Systematic Investigation

A **systematic investigation** is an activity that involves a plan that incorporates structured data collection, either quantitative or qualitative, and data analysis to answer a question.

Examples of systematic investigation tools include:

- Surveys and questionnaires
- Interviews and focus groups
- Creation of a data collection sheet/database
- Other electronic data capture methods (e.g., continuous vital sign monitoring)

**Note:** Not all systematic investigations constitute research.

1. Are you conducting a **systematic investigation**? \*

- Yes, my project involves a plan that incorporates structured data collection (either quantitative or qualitative) and data analysis to answer a question
- No, my project does not fit this criteria

## Generalizable Knowledge

**Generalizable knowledge** is information that expands the knowledge base of an academic discipline or other scholarly field of study. Systematic investigations that are designed to develop or contribute to generalizable knowledge constitute research.

**Quality Improvement/Quality Assessment (QI/QA)** is defined as a data-driven, systematic approach to improving institutional procedures or evaluate program effectiveness. Although QI/QA does involve collecting and analyzing data, if it's scope is intended only to serve the institution, it does not constitute research requiring IRB review and approval.

**Note:** If you anticipate this work may one day be presented at a conference or submitted to a journal.

### 2. Are you intending to produce **generalizable knowledge**?

Note that if you think this work **may** one day be presented at a conference or submitted to a journal, please select "Yes" below. \*

- Yes, results from this project are expected to be applicable to a larger population beyond the sample of data collection or the specific subjects studied OR to be used to develop, test, or support theories, principles, and statements of relationships beyond the study
- No, knowledge gained from the project is not **intended** to be generalizable (it is limited to administrative, financial, legal, quality improvement, or quality assessment efforts to improve institutional processes or evaluate program effectiveness)

**Does your project involve "human subjects"?**

Respond to the following questions to determine whether your project involves "human subjects", according to the Common Rule.

**Human subject** refers to "a living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

## Living People

3. Are you collecting data (specimens or information) from **living** people? \*

- Yes, my project involves collecting data from living individuals
- No, my project only involves collecting data from dead people or cadavers

## Intervening/Interacting with Individuals and/or Collecting Identifiable Data

**Intervening** with individuals could mean you're implementing some kind of procedure that will affect people in their environment. This could mean you're running an experiment and individuals will be asked to complete a task, or it could mean you're delivering a survey or asking them for feedback.

**Interacting** with individuals means you're communicating directly with people in some form, whether that be in person, by phone, via email, through an online survey, or something else.

**Identifiable data** can be broken down into two forms:

1. **direct:** information or specimens that could enable members of the research team to easily determine the individual's identity, such as:
  - social security number
  - full name
  - email address
  - phone number
  - medical record number
2. **indirect:** information or specimens that could be used in combination with other pieces of information to ultimately identify an individual, such as:
  - age
  - gender
  - race
  - ethnicity
  - birthdate
  - occupation
  - employer
  - zip code
  - class section

Let's say you're collecting data from a specific class that meets this semester. Collecting the name of course individuals are enrolled in is not directly identifiable (assuming there is more than 1 student in that class), but if you **also** collect data about participants' birthdates, it's very plausible that you could determine who that is at a later time by knowing those two pieces of information in combination (how many people in the same class have the same birthdate??).

Keep in mind that creating codes to replace a participants' identifiers with a different/random label, which is a common practice, is still considered identifiable if you collect that identifiable information in the first place. Online surveys, even if you don't ask for directly identifiable information, often still collect respondents' email addresses and/or full names, making their responses directly identifiable.

4. Are you **intervening/interacting** with the individuals you're collecting data from AND/OR are you collecting any data that could be considered (directly and/or indirectly) **identifiable** in nature? \*

- My project **does** involve intervening or interacting with people directly, and **will** collect information or specimens that could enable members of the research team to determine the individual's identity, directly OR indirectly
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